## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., et al.,	
Plaintiffs,	) ) ) C.A. No. 08-021 (GMS) (LPS)
V.	) CONSOLIDATED
COBALT LABORATORIES INC., et al.,	) REDACTED –
Defendants.	) PUBLIC VERSION
FOREST LABORATORIES, INC., et al.,	)
Plaintiffs,	)
v.	)
BARR LABORATORIES, INC., et al.,	) C.A. No. 08-022 (GMS) (LPS)
Defendants.	) _
FOREST LABORATORIES, INC., et al.,	)
Plaintiffs,	)
v.	) C.A. No. 08-052 (GMS) (LPS)
DR. REDDY'S LABORATORIES, INC., et al.,	) ) )
Defendants.	)
FOREST LABORATORIES, INC., et al.,	
Plaintiffs,	)
V.	) C.A. No. 08-291 (GMS) (LPS)
ORGENUS PHARMA INC.,	)
Defendant.	) _)

FOREST LABORATORIES, INC., et al.,		
Plaintiffs,	)	
v.	)	C.A. No. 08-336 (GMS) (LPS)
APOTEX INC., et al.,	)	
Defendants.	) )	

# PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANT ORCHID INDIA'S MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION

### AND

## OPENING BRIEF IN SUPPORT OF THEIR CONTINGENT CROSS-MOTION TO TRANSFER

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### I. NATURE AND STAGE OF PROCEEDINGS

On March 3, 2008, Orchid India moved to dismiss the Complaint against it for lack of personal jurisdiction. (D.I. 43.) Orchid India subsequently consented to limited jurisdictional discovery and entered into a stipulation with Plaintiffs extending Plaintiffs' time to respond to its motion until June 27, 2008. (D.I. 79.)

Plaintiffs hereby submit this brief in response to Orchid India's motion to dismiss, as well as in support of Plaintiffs' Contingent Cross-Motion for Transfer (filed herewith).

### II. SUMMARY OF ARGUMENT

Orchid India has purposefully availed itself of the United States market, including

Delaware, for years. Although it does not sell its extensive line of products directly to

drugstores, Orchid India has formed a wide-ranging network of distributors to take advantage of
the lucrative United States generic pharmaceuticals market

Orchid India has filed over forty Abbreviated New Drug

Applications ("ANDAs") in the United States to date, and shows no signs of stopping.

In this instance, Orchid India has submitted ANDA No. 90-044 to the FDA to market a generic version of Plaintiffs' blockbuster drug NAMENDA® (memantine hydrochloride) throughout the United States. But unlike the twelve other ANDA filers in this case, Orchid India has refused to consent to this Court's jurisdiction. Orchid India's steadfast refusal to consent is puzzling. Orchid India's motion to dismiss, moreover, offers only superficial denials and self-serving declarations. In view of its extensive general contacts with the United States and its specific contacts with Delaware, this Court has grounds to exercise any of three different kinds of jurisdiction over Orchid India.

First, this Court can exercise dual jurisdiction over Orchid India. In accordance with this Court's recent decisions, dual jurisdiction may be exercised pursuant to Delaware's long-arm

statute over a non-resident defendant with an intent to serve the United States market, so long as
there is no evidence that Delaware would be excluded from its marketing and distribution efforts.
Orchid India will thus be able to continue its stated goal of
targeting "the world's largest and most profitable generics market," the United States.
Second, this Court can exercise general jurisdiction over Orchid India. Orchid India
plainly has the requisite contacts for general jurisdiction under Delaware's long arm statute,
including a wholly-owed subsidiary in Delaware, Orchid Pharma.
Orchid India's Annual Reports also
confirm, time and time again, Orchid India's strong desire to be a major player in the United
States generic pharmaceuticals market, which necessarily includes Delaware.
Third, this Court can exercise specific jurisdiction over Orchid India in view of the
contacts between Delaware, ANDA No. 90-044, and its proposed generic NAMENDA®
products.
And Orchid India's allegations
of infringement and invalidity of the patent-in-suit have caused tortious injury to a Delaware
corporation, Plaintiff Forest Labs.

And if these separate bases for jurisdiction are not enough, this Court could also exercise jurisdiction over Orchid India under the principles of alter ego and agency.

The "minimum contacts" requirements of due process are also plainly satisfied here, regardless of the type of jurisdiction that the Court may choose to exercise over Orchid India. Moreover, both Delaware and Plaintiffs have strong interests in adjudicating this action in Delaware. The twenty-one other Defendants in this case have already consented to jurisdiction. and Orchid India has not provided any evidence that the burden of litigating this case in Delaware is any greater than the burden of litigating in any other state. Orchid India's motion seeks nothing more than to substitute is own (arguable) convenience for the convenience of Plaintiffs and the twenty-one remaining Defendants.

But in the event that this Court ultimately decides not to exercise jurisdiction over Orchid India, Plaintiffs respectfully request that their claims against Orchid India be transferred to the District of New Jersey. Orchid India has already indicated that it would be amenable to suit in that forum.

#### Ш. STATEMENT OF FACTS

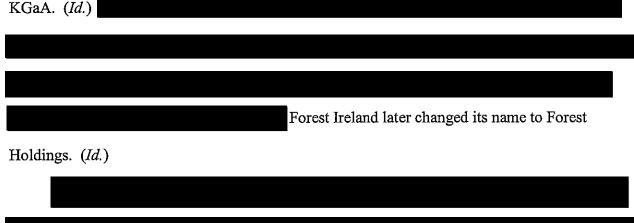
#### The Plaintiffs A.

Plaintiff Forest Laboratories, Inc. ("Forest Labs") is an innovative pharmaceutical company that identifies, develops, and delivers new pharmaceutical products, focusing on the therapeutic areas of the central nervous, cardiovascular and respiratory systems. Plaintiff Forest Laboratories Holdings, Ltd. ("Forest Holdings") is a wholly-owned subsidiary of Forest Labs. Plaintiffs Merz Pharma GmbH & Co KGaA and Merz Pharmaceuticals GmbH

(collectively "Merz") are international pharmaceutical companies engaged in the research and development of drugs for the treatment of psychiatric and neurological disorders.

#### В. The Patent-In-Suit

On March 21, 1990, the three named inventors listed on the face of U.S. Patent No. 5,061,703 ("the '703 patent"), entitled "Adamantane Derivatives in the Prevention and Treatment of Cerebral Ischemia," executed an assignment of their interest in the '703 patent to Merz + Co. GmbH & Co. (D.I. 72 at 8.) This assignment was recorded with the U.S. Patent and Trademark Office ("PTO") on May 7, 1990. (Id.) As also recorded with the PTO on May 1, 2002, Merz + Co. GmbH & Co. subsequently changed its name to Merz Pharma GmbH & Co.



Forest Labs is also the holder of New

Drug Application ("NDA") No. 21-487 for memantine hydrochloride tablets, which are commercially marketed in the United States under the brand name NAMENDA®. (Id. at 9.)

Orchid has suggested that Forest Labs, as a licensee, may not have standing to assert a claim under the '703 patent. (D.I. 44 at 9.) This suggestion is wrong. Forest Labs plainly has standing to sue here, since the assignee of the '703 patent (Merz) is also a named Plaintiff. See Propat Int'l Corp. v. Rpost, Inc., 473 F.3d 1187, 1193 (Fed. Cir. 2007) (holding that exclusive licensee may sue for infringement by joining patent owner in the action against the accused infringer).

NAMENDA<sup>®</sup> is approved by the United States Food and Drug Administration ("FDA") for the treatment of moderate to severe dementia of the Alzheimer's type. The '703 patent is listed in the U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") as covering NAMENDA<sup>®</sup>.

### C. The ANDA Defendants

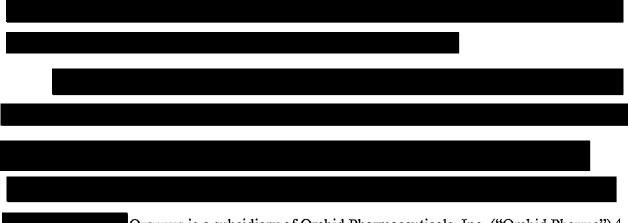
Sixteen companies have recently submitted Abbreviated New Drug Applications ("ANDAs") with accompanying Paragraph IV certifications to the FDA, pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act, seeking approval to commercially manufacture, use and sell generic versions of NAMENDA® prior to the expiration of the '703 patent. Under the provisions of the Hatch-Waxman Act, the submission of these ANDAs constitute infringement of the '703 patent. See 35 U.S.C. § 271(e)(2)(A). In order to trigger a stay of approval of the ANDAs, Plaintiffs were required to file an action for infringement of the '703 patent within forty-five days of receiving notice of the respective Paragraph IV certifications. See 21 U.S.C. § 355(j)(5)(B)(iii). As a result, Plaintiffs filed a series of actions in this District against the various Defendants (Civil Action Nos. 08-021, -022, -052, -291, and -336). All five actions have since been consolidated. (D.I. 76, 83.)

Orchid Chemicals & Pharmaceuticals, Ltd. ("Orchid India") is one of only two defendants who have contested personal jurisdiction in this District.<sup>2</sup> Orchid India is an Indian corporation that manufactures numerous generic pharmaceuticals for sale throughout the United States, including in this District.

The only other defendant contesting personal jurisdiction in Delaware is Orgenus Pharma, Inc. ("Orgenus"),

Orgenus filed its motion to dismiss on June 19, 2008. (D.I. 87.)

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Organus is a subsidiary of Orchid Pharmaceuticals, Inc. ("Orchid Pharma"),<sup>4</sup> a Delaware corporation formed by Orchid India. (Rao Dep. Tr. 24:16-25:16.)

### IV. ARGUMENT

The law of the Federal Circuit governs personal jurisdiction issues in patent infringement cases. See Hildebrand v. Steck Mfg. Co., 279 F.3d 1351, 1354 (Fed. Cir. 2002). To decide whether personal jurisdiction exists over a non-resident defendant, "the court must determine whether jurisdiction lies under both the applicable state long-arm statute and the Due Process Clause of the Federal Constitution." See Viam Corp. v. Iowa Export-Import Trading Co., 84 F.3d 424, 427 (Fed. Cir. 1996).

When personal jurisdiction over a defendant is challenged by a motion to dismiss, the plaintiff bears the burden of showing the basis for jurisdiction. *See Power Integrations, Inc. v. BCD Semiconductor Corp.*, No. 07-633-JJF-LPS, 547 F. Supp. 2d 365, 2008 WL 1775415, at \*3 (D. Del. April 11, 2008). To meet this burden, the plaintiff need only make a *prima facie* 

<sup>3</sup> See Deposition

<sup>4</sup> Orchid Pharma is a Defendant in this action and has not contested jurisdiction in Delaware.

showing that personal jurisdiction is conferred by statute. *Id.* All factual inferences, moreover, "must be viewed in the light most favorable to the plaintiff." *Id.* 

## A. Personal Jurisdiction Over Orchid India Is Proper Under Delaware's Long-Arm Statute

The Delaware long-arm statute has been construed "liberally so as to provide jurisdiction to the maximum extent possible. In fact, the only limit placed on [the statute] is that it remain within the constraints of the Due Process Clause." *Power Integrations*, 2008 WL 1775415, at \*4 (internal quotation marks omitted) (*quoting Boone v. Oy Partek Ab*, 724 A.2d 1150, 1157 (Del. Super. Ct. 1997)). The statute provides a number of bases for personal jurisdiction:

- (c) As to a cause of action brought by any person arising from any of the acts enumerated in this section, a court may exercise personal jurisdiction over any nonresident, or a personal representative, who in person or through an agent:
- (1) Transacts any business or performs any character of work or service in the State;
- (2) Contracts to supply services or things in this State;
- (3) Causes tortious injury in the State by an act or omission in this State;
- (4) Causes tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State.

10 Del. Code § 3104(c). Subsections (c)(1)-(c)(3) confer "specific" jurisdiction over a non-resident defendant, while subsection (c)(4) confers "general" jurisdiction. *Boone*, 724 A.2d at 1155.

### 1. This Court Should Exercise Dual Jurisdiction Over Orchid India

### (a) The Relevant Legal Standards

In several recent decisions, Delaware courts have cited the concept of dual jurisdiction as a means to exercise personal jurisdiction over a non-resident defendant. See Power Integrations,

2008 WL 1775415, at \*5. It is well-established that personal jurisdiction may exist when a non-resident corporation places its products in the marketplace and thereby creates sufficient jurisdictional contacts with any state in which its products may eventually be sold. *Id.* at \*5; see also Asahi Metal Indus. Co. v. Superior Court of Cal., 480 U.S. 102, 112 (1987); Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1564 (Fed. Cir. 1994); Renner v. Lanard Toys Ltd., 33 F.3d 277, 280 (3d Cir. 1994). To reconcile this "stream of commerce theory" with subsections (c)(1) and (c)(4) of Delaware's long-arm statute, Delaware courts rely upon the concept of dual jurisdiction. See Power Integrations, 2008 WL 1775415, at \*5-6.

This Court has previously applied the concept of dual jurisdiction to defendants in patent infringement cases. See LG.Phillips LCD Co., Ltd. v. Chi Mei Optoelectronics Corp., Nos. 06-726-JJF, 07-357-JJF, -- F. Supp. 2d --, 2008 WL 1897687, at \*5 (D. Del. Apr. 29, 2008) (finding personal jurisdiction over manufacturer accused of patent infringement, in part, because there was evidence of a world-wide distribution network that caused the allegedly infringing products to be sold and distributed in Delaware); Power Integrations, 2008 WL 1775415, at \*10 (denying dismissal of patent infringement action against foreign manufacturer and ordering limited jurisdictional discovery to determine whether there was dual jurisdiction).

In Delaware, "the touchstone of the dual jurisdiction analysis is *intent and purpose to* serve the Delaware market." Id., at \*6. The Delaware market, however, does not need to be specifically targeted. Instead, a "non-resident firm's *intent to serve the United States market is* sufficient to establish an intent to serve the Delaware market, unless there is evidence that the firm intended to exclude from its marketing and distribution efforts some portion of the country that includes Delaware." Id. at \*7 (emphasis added).

(b) Orchid India Has A Clear Intent To Serve The United States, Including Delaware, Thus Satisfying The Requirements For Dual Jurisdiction

Dual jurisdiction should be exercised over Orchid India in this case. Orchid India has shown an indisputable intent to serve the United States market and distribute its proposed memantine hydrochloride products throughout the United States, including Delaware. Orchid India has developed generic drug products specifically for distribution and sale in the United States.<sup>5</sup> In its Annual Reports, for example, Orchid India expressly stated that it has targeted the United States because the United States is "the world's largest and most profitable generics market, accounting for at least 50% of the global generics sale and a larger profit share" (Ex. 3 at OCP\_0000585), and because the "US market... offers distinctive incentives in terms of 180-day exclusivities related to the Paragraph IV [ANDAs and] first-to-file products" (Id. (emphasis added);

Orchid India also has a corporate presence in Delaware – Orchid Pharma, a wholly-owned subsidiary,

In its

Annual Reports, Orchid India stated that it formed Orchid Pharma "to cater to the more demanding requirements of business development and logistical coordination in the US."

Orchid India has also described Orchid Pharma as Orchid India's "agent for filing of regulatory submissions with the US FDA."

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See Orchid India Annual Report 2006-07, Exhibit 3, at OCP\_00000622.

<sup>6</sup> See Orchid Pharmaceuticals, Inc., Delaware Certificate of Incorporation, Exhibit 4, at OPI\_00000001.

<sup>&</sup>lt;sup>7</sup> See Orchid India Annual Report 2005-06, Exhibit 5, at OCP\_00000460.

<sup>8</sup> See Orchid India Annual Report 2004-05, Exhibit 6, at OCP\_00000368.

Orchid India has filed at least forty ANDAs with the FDA to market various generic drug products throughout the United Sates. (Ex. 3 at OCP 00000611.)<sup>9</sup> These extensive filings are consistent with Orchid India's stated goal of "aggressively filing" ANDAs in the this country. (Ex. 5 at OCP 00000493.) Not surprisingly, Orchid India expects the "increased filings and approvals of ANDAs . . . to increase revenues and profits significantly." (Ex. 3 at OCP 00000594; see also id. at OCP 00000573-574.) Orchid India has also purchased and constructed factories in India, specifically in accordance with FDA standards, to "help service the US generics market." (Ex. 5 at OCP\_00000485, 488-89, 493; Ex. 3 at OCP\_00000573-74.)

To distribute its generic products throughout the United States, Orchid India has entered into "strategic alliances with distribution partners." (Ex. 3 at OCP 00000598.)

A generic drug company may not market a given drug in the United States unless that drug is the subject of an FDA-approved ANDA. 21 U.S.C. § 355(a), (j).

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11 Plaintiffs were unable to confirm this fact, however, because Orchid India refused to provide jurisdictional discovery on this issue. (D.I. 71 (Requests for Production) at 10-11.)

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Each of Orchid India's agreements grants its U.S. distributor exclusive rights to market, distribute, and sell certain Orchid India products within Delaware and throughout the United States. (Ex. 3 at OCP 00000599.)

Orchid India's distribution channels in the United States have proven lucrative. In 2006-07, Orchid India's sales in the United States produced over 40% of its total revenue. (Ex. 3) at OCP 00000550, 569.) Since 2005, Orchid India has generated over \$200 million in revenue from the United States.<sup>13</sup> In 2006-07 alone, Orchid India generated \$112 million in revenue from marketing agreements for its first six products sold in the United States. (Ex. 3 at OCP 00000573.) Acknowledging the role of the United States in its success, Orchid India told its shareholders that "[t]he buoyancy in performance [for fiscal year 2005-06] was triggered to a major extent by the successful entry of your Company into the US generics market." (Ex. 5 at OCP 00000456; see also Ex. 3 at OCP 00000587-88, 590-91.)

The same channels that Orchid India currently uses to distribute its products would also be used to distribute the proposed generic NAMENDA® products if the FDA approves Orchid

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Orchid India's actions plainly avail Orchid India of the Delaware market, and allow the Court to exercise dual jurisdiction over Orchid India. See LG. Phillips, 2008 WL 1897687, at \*5-6 (finding personal jurisdiction over manufacturer accused of patent infringement, in part, because there was evidence of a world-wide distribution network that caused the allegedly infringing products to be sold and distributed in Delaware); Energy Transp. Group, Inc. v. William Demant Holding A/S, No. C.A. 05-422 GMS, 2008 WL 78748, at \*4 (D. Del. Jan. 4, 2008) (finding personal jurisdiction over foreign manufacturer in patent infringement action, in part, because manufacturer placed products in stream of commerce and knew that they would be sold in the United States and Delaware); Eason v. Linden Avionics, Inc., 706 F. Supp. 311, 324 (D.N.J. 1989) ("[Defendant] cannot avoid being subject to the jurisdiction of a state simply by arranging for the indirect distribution of its goods rather than entering a local market independently.... Foreign manufacturers cannot insulate themselves from jurisdiction by erecting a sophisticated web of distribution.").

### 2. This Court Should Exercise General Jurisdiction Over Orchid India

### (a) The Relevant Legal Standards

Subsection (c)(4) of Delaware's long-arm statute confers general jurisdiction over a non-resident defendant. *Boone*, 724 A.2d at 1155. General jurisdiction arises when the defendant has continuous and systematic contacts with the forum state, even if those contacts are not related to the particular cause of action. *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414-15 (1984). Continuous and systematic contacts are present if the defendant or its agent "regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or thing used or consumed in the State."

The fact that a company does not manufacture the product or has no employees, agents or real property in the forum is not dispositive of whether the court can exercise general jurisdiction. *See Wright v. Am. Home Prods.*, 768 A.2d 518, 530-31 (Del. Super. 2000) (finding general and specific jurisdiction over French pharmaceutical companies, in part, because companies engaged in long-standing efforts to market the product throughout the United States); *See also Eli Lilly & Co. v. Mayne Pharma (USA) Inc.*, 504 F. Supp. 2d 387, 393-95 (S.D. Ind. 2007) (holding that an ANDA filer's revenues from other products, sold in forum through wholesalers, support the exercise of general jurisdiction over ANDA filer in infringement action under Hatch-Waxman Act).

### (b) Orchid India's Contacts With Delaware Should Be Considered General And Systematic For General Jurisdictional Purposes

Orchid India's reliance on *Merck*<sup>14</sup> in support of its position that there is no general jurisdiction over it in Delaware (D.I. 44 at 2-3) is misplaced. Instead, *Merck* is factually distinguishable from this case on a number of grounds. The defendant in *Merck* had a principal place of business in New York, and an identical patent infringement action was pending in the Southern District of New York. *Merck*, 179 F. Supp. 2d at 370. In contrast, Orchid India has a principal place of business in India, and no other action for infringement of the '703 patent is presently pending against Orchid India in another district court. In addition, the plaintiff in *Merck* conceded that there was no specific jurisdiction over the defendant. *Id.* at 371. Plaintiffs in this case have made no such concession, and contend that the Court may exercise specific jurisdiction over Orchid India on several bases (discussed *infra*).

But most importantly for general jurisdiction purposes, there is evidence here that Orchid India has continuous and systematic contacts with Delaware. First, Orchid India has a Delaware subsidiary, Orchid Pharma,

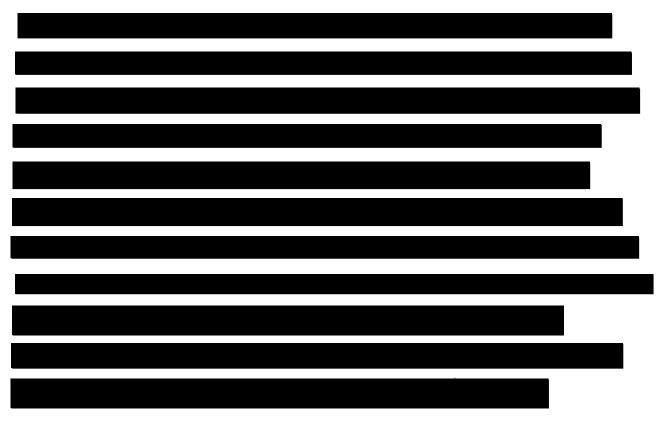
Orchid India's 2004-05 Annual Report describes Orchid Pharma as Orchid India's "agent for filing of regulatory submissions with the US FDA . . . . "

(Ex. 6 at OCP\_00000368.)<sup>15</sup>

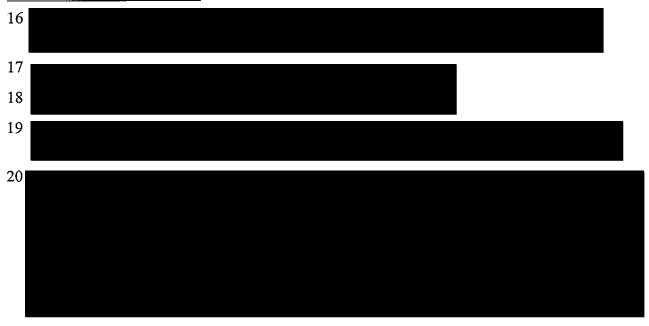
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<sup>&</sup>lt;sup>14</sup> Merck & Co., Inc. v. Barr Labs., Inc., 179 F. Supp. 2d 368 (D. Del. 2002).



Even if *Merck* were applicable to this case (and it is not), the Federal Circuit and this Court have not applied the reasoning in *Merck* in recent decisions. *See Commissariat a* 



21 See AAIPharma, Inc. Delaware Certificate of Incorporation, Exhibit 22.

L'Energie Atomique v. Chi Mei Optoelectronics Corp., 395 F.3d 1315, 1317-22 (Fed. Cir. 2005) (vacating dismissal of patent infringement action for lack of personal jurisdiction even though defendant had no operations, employees, or property in Delaware, was not registered to do business in Delaware, and did not transact business directly in Delaware); LG.Phillips, 2008 WL 1897687, at \*2, 5 n.2 (explicitly declining to follow *Merck* and denying motion to dismiss patent infringement action for lack of personal jurisdiction even though defendant had no employees in Delaware, was not registered to do business in Delaware, did not own or lease property in Delaware, and did not sell its products directly in Delaware); Power Integrations, 2008 WL 1775415, at \*1, 10 (declining to dismiss patent infringement action for lack of personal jurisdiction even though defendant had no offices, employees, property, or bank accounts in Delaware, was not registered to do business in Delaware, and did not sell products directly in Delaware); see also Beverly Hills Fan, 21 F.3d at 1560, 1572 (reversing dismissal of patent infringement action for lack of personal jurisdiction even though accused manufacturer had no assets or employees in forum, was not registered to do business in forum, and did not sell products directly in forum).

### This Court Should Exercise Specific Jurisdiction Over Orchid India 3. (a) The Relevant Legal Standards

A court may exercise specific jurisdiction over a defendant when the particular cause of action arises from defendant's activities within the forum state. See Helicopteros, 466 U.S. at 414. The types of activities that give rise to specific personal jurisdiction over defendants in Delaware are set forth in the Delaware long-arm statute. Subsection (c)(1) allows a court to exercise personal jurisdiction over a non-resident who "[t]ransacts any business or performs any character of work of service in the State . . . . " 10 Del. Code § 3104(c)(1). Subsection (c)(3)

authorizes personal jurisdiction over a non-resident who "[c]auses tortious injury in the State by an act or omission in this State . . . . " 10 Del. Code § 3104(c)(3). Under Delaware law,

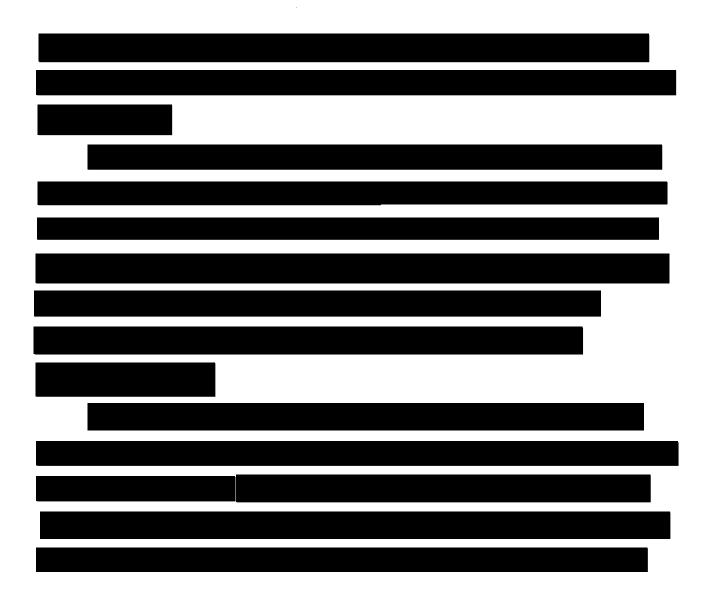
[w]here personal jurisdiction is asserted on a transactional basis, even a single transaction is sufficient if the claim has its origin in the asserted transaction. Thus, if the claim sought to be asserted arose from the performance of business or the discharge of the contract, no further inquiry is required concerning any other indicia of the defendant's activity in this state.

Similarly, where the claim is one for tortious injury under subsection (c)(3), a single "act or omission" in the State in which the injury was caused will suffice.

LaNuova D & B, S.p.A v. Bowe Co., 513 A.2d 764, 768 (Del. 1986) (internal citations omitted) (emphasis added); see also TriStrata Tech., Inc. v. Emulgen Labs., Inc., 537 F. Supp. 2d 635, 640-41 (D. Del. 2008) (finding specific jurisdiction over manufacturer in patent infringement action in part because manufacturer contracted with third party to market its product through nationwide e-mail broadcast).

> The Cause Of Action Against Orchid India Arises, In Part, (b) From Activities Related To ANDA No. 90-044 Which Occurred In Delaware

Orchid India mistakenly argues that this action did not "arise out of" its contacts with Delaware. (D.I. 44 at 8-10.) But Orchid India concedes, as it must, that the jurisdictionally relevant facts are those "surrounding the preparation and submission of ANDA No. 90-044." (D.I. 44 at 9.) Orchid India's proposed memantine hydrochloride tablets result from activities that have an unassailable connection to Delaware. These activities clearly satisfy the requirements of subsection (c)(1) of the Delaware long-arm statute: "transacts any business or performs any character of work or service in the state." 10 Del. Code § 3104(c)(1).





As these are all "facts surrounding the preparation and submission of ANDA No. 90-044," they are sufficient to support the exercise of specific jurisdiction over Orchid India.

## (c) Orchid India Has Caused Tortious Injury To Forest Labs In Delaware

Specific jurisdiction over Orchid India may also be exercised by the Court because Orchid India caused tortious injury to at least one Plaintiff in Delaware, thus satisfying the requirements of subsection (c)(3) of the Delaware long-arm statute.

The value of Forest Labs' stock, as well as its future business opportunities, may suffer as a result Orchid India's allegations. Therefore, the most realistic situs of injury to Plaintiffs in the United States is Delaware, where Plaintiff Forest Labs is incorporated and where the economic injury to Forest Labs would occur.

The question of whether these facts, standing alone, give rise to specific personal jurisdiction over an ANDA defendant in a plaintiff's home forum is an important but unresolved issue in ANDA litigation. The Federal Circuit has held that submitting an ANDA containing a Paragraph IV certification to the FDA in Maryland does not give rise to specific personal jurisdiction over the ANDA filer in Maryland. See Zeneca Ltd. v. Mylan Pharms., Inc., 173 F.3d

<sup>23</sup> 

<sup>24</sup> 

<sup>25</sup> See Orchid India Paragraph IV Notice, Exhibit 28.

829, 831-32 (Fed. Cir. 1999). But the *Zeneca* court did not address whether the sending of a Paragraph IV notice, by itself, gives rise to personal jurisdiction over the ANDA filer in a plaintiff's state of incorporation. Plaintiffs have found no reported decision that squarely addresses this issue, despite its importance to ANDA litigations.<sup>26</sup>

The absence of clear precedent has caused, and continues to cause, confusion, needless litigation, and waste of judicial resources, particularly in cases in which the patentee faces multiple ANDA defendants incorporated or headquartered in numerous different jurisdictions. Here, of the twenty-three Defendants, three are Delaware corporations located in New Jersey, two are Delaware corporations located in Florida, two are Delaware corporations located in New York, one is a Delaware corporation located in Pennsylvania, two are New Jersey corporations located in New Jersey, two are New York corporations located in New York, one is a Minnesota corporation located in Minnesota, one is a Virginia corporation located in Maryland, one is a West Virginia corporation located in West Virginia, two are Canadian companies, one is a Croatian company, and five are Indian companies.<sup>27</sup>

To argue that there is no specific jurisdiction, Orchid India's reliance on Foster Wheeler Energy Corp. v. Metallgesellschaft AG, No. 91-214-SLR, 1993 WL 669447, at \*5 (D.Del. Jan. 4, 1993) (D.I. 44 at 9), is misplaced. The patent infringement action at issue in Foster Wheeler did not involve the unique challenges that ANDA litigations present, including the situation where a patentee faces multiple ANDA defendants with principal places of business in numerous jurisdictions.

Where multiple ANDA defendants are involved in a litigation, it is likely that they have all filed their ANDAs with the FDA on the first allowable day. This result follows from new incentives created by the 2003 amendments to the Hatch-Waxman Act, providing that all who file on the first allowable day have an equal entitlement to the 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb). The patentee, consequently, receives multiple Paragraph IV notices at the same time and has essentially a single 45 day period in which to file against all defendants. As a result, the need for guidance on this jurisdictional issue is greater than ever.

Requiring Plaintiffs to sue each Defendant in its home forum would result in enormous duplication of effort, waste of judicial resources, and possibly inconsistent results. On the other hand, requiring Defendants to litigate in Forest Labs' home forum comports with due process (discussed *infra*), because Defendants can easily foresee that sending a Paragraph IV notice to a Delaware corporation will result in litigation in Delaware. Resolution of this important jurisdictional question would bring much-needed predictability and certainty to ANDA litigations and would preserve scarce judicial resources often expended in adjudicating motions to dismiss.

## 4. This Court Should Exercise Personal Jurisdiction Over Orchid India On The Basis Of Alter Ego And Agency

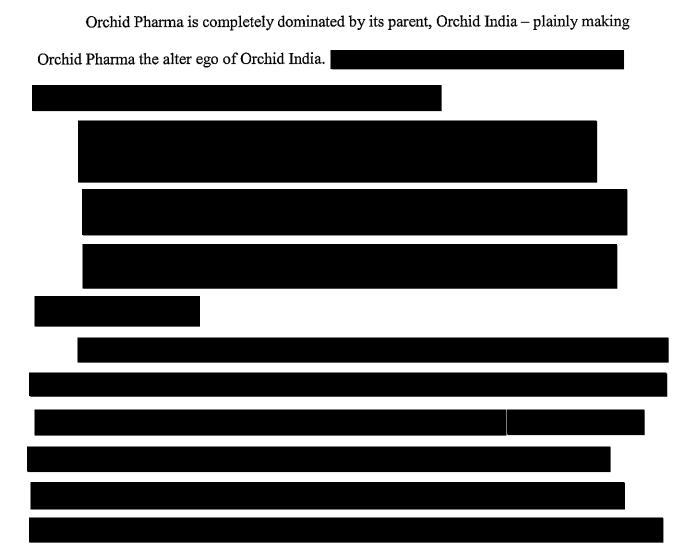
### (a) The Relevant Legal Standards

Delaware law allows a court to find jurisdiction over a foreign parent corporation for the acts of its Delaware subsidiary on either alter ego or agency grounds. *E.I. duPont de Nemours & Co. v. Rhodia Fiber & Resin Intermediates, S.A.S.*, 197 F.R.D. 112, 122 (D. Del. 2000). "A subsidiary corporation may be deemed the alter ego of its corporate parent where there is a lack of attention to corporate formalities, such as where assets of two entities are commingled, and their operations intertwined." *In re Phillips Petroleum Sec. Litig.*, 738 F. Supp. 825, 838 (D. Del. 1990) (internal quotation marks omitted). "An alter ego relationship might also lie where a corporate parent exercises complete domination and control over its subsidiary." *Id.* at 838-39 (internal quotation marks omitted).

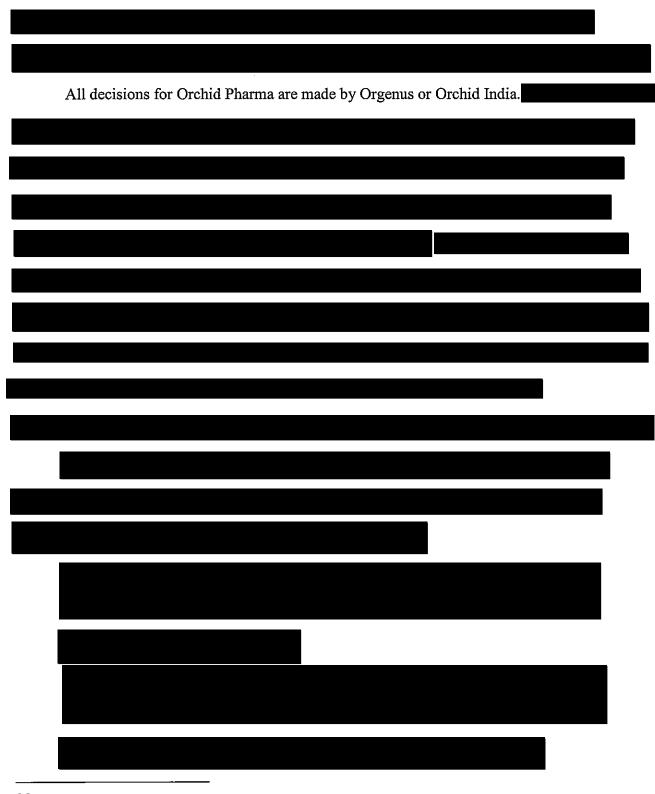
Under the concept of agency, a court may attribute the actions of one corporation to another when one corporation acts on behalf of or at the direction of the other. *Rhodia Fiber*, 197 F.R.D. at 122. A finding of an agency relationship requires a close connection between the relationship of two corporations and the cause of action. *See Wesley-Jessen Corp. v. Pilkington* 

Visioncare, Inc., 863 F. Supp. 186, 189 (D. Del. 1993) (finding personal jurisdiction over foreign corporation in patent infringement suit under agency theory because foreign corporation and Delaware corporation had close corporate and business connections and acted as two arms of the same business group in common pursuit).

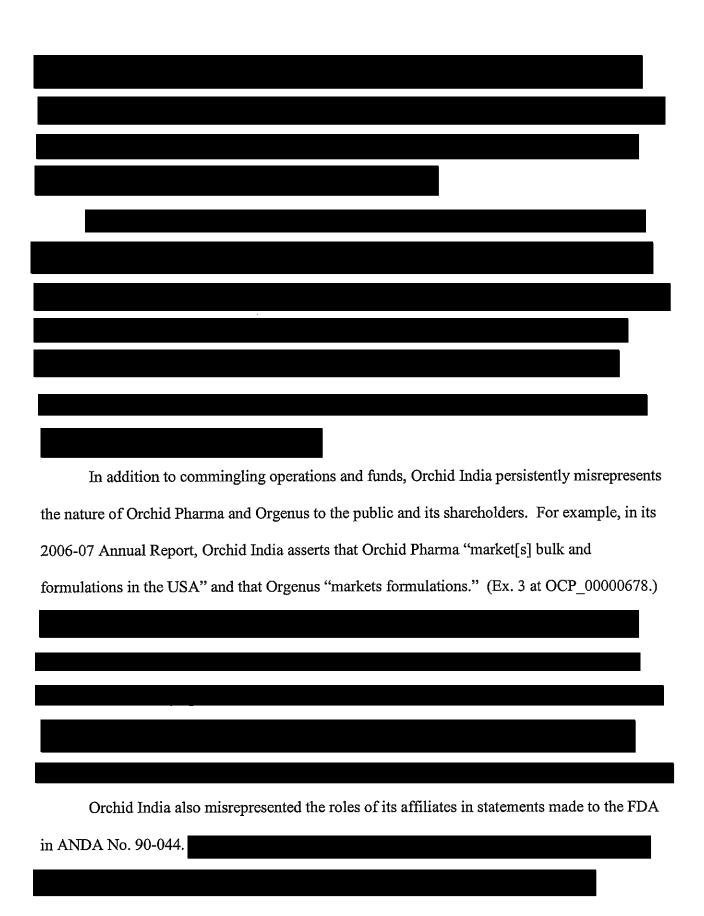
#### Orchid Pharma Is The Alter Ego Of Orchid India (b)



<sup>28</sup> See Orchid Pharmaceuticals, Inc. 2006 Delaware Franchise Tax Report, Exhibit 29, at OPI 00000007.



<sup>29</sup> See Orchid Pharmaceuticals, Inc. 2004 Delaware Franchise Tax Report, Exhibit 30, at OPI 00000004; Orchid Pharmaceuticals, Inc. 2005 Delaware Franchise Tax Report, Exhibit 31, at OPI\_00000006.



Orchid India also misapprehends the relevant legal standards in relying upon *C.R. Bard* in support of its position that Orchid Pharma is not Orchid India's alter ego.<sup>30</sup> (D.I. 44 at 12). In that case, the parent corporation was a holding company with a board of directors *separate* from its subsidiary. *Bard*, 997 F. Supp. at 558. Moreover, neither the parent nor the subsidiary was incorporated in Delaware. *Id.* Here, Orchid India is not a holding company – it is a controlling (and independently functioning) parent.

Additionally, as outlined above, there is evidence in this case, absent from *Bard*, that the finances of Orchid India and Orchid Pharma were commingled and that Orchid India has misrepresented the nature of Orchid Pharma's business.

### (c) Orchid Pharma Acts As Orchid India's Agent

This Court may also exercise jurisdiction over Orchid India on agency grounds, given that Orchid Pharma and Orgenus plainly act as Orchid India's agents in the United States. As evidenced by its annual reports, Orchid India decided to develop generic drug products for sale in the United States. (Ex. 3 at OCP\_00000585-88, 622; Rao Dep. Tr. 33:6-20.) Before these products could be sold, however, the FDA had to approve an ANDA for each product that Orchid India would place in the United States market. *See* 21 U.S.C. § 355(j).

<sup>30</sup> C.R. Bard, Inc. v. Guidant Corp., 997 F. Supp. 556, 558 (D. Del. 1998).

Orchid India, Orchid Pharma and Orgenus thus work together as three "arms of the same business group" to file ANDAs in the United States, including ANDA No. 90-044, and their specific roles are not relevant for purposes of agency. *See Wesley-Jessen*, 863 F. Supp. at 189 (attributing distribution subsidiary's Delaware contacts to manufacturing subsidiary where the entities were "two arms of the same business group in their attempt to achieve the common goal of selling" the allegedly infringing products "in Delaware and other markets").

Orchid India incorrectly relies on *Sears* and *Monsanto* in support of its position that there is no personal jurisdiction over Orchid India on agency grounds.<sup>31</sup> (D.I. 44 at 13-14.) *Sears* is inapposite. The court's dismissal of that action did not turn on whether an agency relationship existed. Instead, the Court found that the Delaware long-arm statute did not confer jurisdiction over the subsidiaries not incorporated in Delaware. *Id.* at 1226-28. In this case, the Delaware long-arm statute would confer jurisdiction over Orchid India because its agent, Orgenus, is the alter ego of a Delaware corporation – Orchid Pharma.

Likewise, *Monsanto* is readily distinguishable. The parent company in *Monsanto*, unlike Orchid India, was a holding company. 443 F. Supp. 2d at 638. In addition, the court in *Monsanto* found that there was no specific or general jurisdiction over the parent company. *Id.* at 645-47. In this case, there is both specific and general jurisdiction over Orchid India. Finally,

<sup>31</sup> Sears, Roebuck & Co. v. Sears plc, 752 F. Supp. 1223, 1226-27 (D. Del. 1990); Monsanto Co. v. Syngenta Seeds, Inc., 443 F. Supp. 2d 636, 644-647 (D. Del. 2006).

there is evidence in the present case, absent in *Monsanto*, of a close connection between the relationship of Orchid India, Orchid Pharma, Orgenus and the ANDA that is the subject of this suit.

#### В. Exercising Personal Jurisdiction Over Orchid India Is Consistent With The **Due Process Clause**

To subject a non-resident defendant to personal jurisdiction, the Due Process Clause requires a finding of "minimum contacts" between the non-resident defendant and the forum state, "such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945). The defendant's contacts must be of a nature that would cause it to reasonably foresee that it might be "haled into court" in the forum as a result of its conduct. See World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 297 (1980).

The contacts that are necessary to satisfy the Due Process Clause depend on the type of personal jurisdiction that is asserted over the non-resident defendant. For dual jurisdiction, due process is satisfied if the defendant has established minimum contacts with a given forum by placing products in the stream of commerce. See Beverly Hills Fan, 21 F.3d at 1568; Motorola, Inc. v. PC-Tel, Inc., 58 F. Supp. 2d 349, 353-356 (D. Del. 1999). For general jurisdiction, due process is satisfied by showing sufficient contacts between the forum and the foreign corporation. Helicopteros, 466 U.S. at 414. And for specific jurisdiction, the requirements of due process are met by showing a relationship between the foreign defendant, the forum, and the litigation. Id.

Orchid India's contacts with Delaware satisfy the due process requirements of all three tests.

These distribution

channels satisfy both the dual and general jurisdiction requirements of due process.

• Orchid India incorporated Orchid Pharma, its wholly-owned subsidiary, in Delaware to act as its agent (Ex. 6 at OCP\_00000368);

Given these numerous contacts, Orchid India should reasonably have anticipated being haled into Delaware court. This Court's exercise of personal jurisdiction over Orchid India is, therefore, consistent with the Due Process Clause.

These minimum contacts, combined with "other factors," establish that "the assertion of personal jurisdiction [over Orchid] would comport with 'fair play and substantial justice." Burger King Corp. v. Rudzewicz, 471 U.S. 462, 476 (1985). "Other factors" this Court should consider include, inter alia, (a) the burden on the defendant, (b) the forum State's interest in adjudicating the dispute, (c) the plaintiff's interest in obtaining convenient and effective relief,

and (d) the interstate judicial system's interest in obtaining the most efficient resolution of controversies. *See id.* at 477. Only in "rare situation[s]" are the "plaintiff's interest and the state's interest in adjudicating the dispute in the forum . . . so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." *Beverly Hills Fan*, 21 F.3d at 1568. This is not such a situation.

Both Delaware and the Plaintiffs have strong interests in adjudicating this action here. Asserting personal jurisdiction over Orchid India would support Plaintiffs' "interest in obtaining convenient and effective relief," *Burger King*, 471 U.S. at 477, and Delaware's "substantial interest in cooperating with other states to provide a forum for efficiently litigating [Plaintiffs'] cause of action," *Beverly Hills Fan*, 21 F.3d at 1568.

Over a dozen generic companies have filed ANDAs with respect to Plaintiffs' blockbuster NAMENDA® brand drug. (D.I. 1 of -021; D.I. 1 of -022; D.I. 1 of -052; D.I. 1 of -291; D.I. 1 of -336.) Every single Defendant, save Orchid India and its subsidiary, has consented to jurisdiction in this Court. (D.I. 30, 33, 35, 42, 47, 49, 94 of -021; D.I. 18, 19 of -022; D.I. 49, 55, 71, 72, 90 of -052.) Each Defendant has raised issues related to infringement and validity of the '703 patent. *See id.* If Plaintiffs were forced to litigate in multiple forums, Defendants would have multiple bites at the apple, since a finding of invalidity in one case would benefit all Defendants. *See generally Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971). Moreover, because each ANDA is designed to obtain permission to market the proposed generic product throughout the United States, Delaware's assertion of personal jurisdiction over Orchid India will spare other states "the burden of providing a forum for [Plaintiffs] to seek redress" for the infringement. *Beverly Hills Fan*, 21 F.3d at 1568.

Furthermore, "Delaware has an interest in discouraging injuries that occur within the state, which extends to patent infringement actions such as the one here." *Energy Transp.*, 2008 WL 78748, at \*5 (*citing Beverly Hills Fan*, 21 F.3d at 1568). This Court "is part of the exclusive mechanism established by Congress for the vindication of patent rights." *Beverly Hills Fan*, 21 F.3d at 1568. Delaware's interest is heightened in this case because a Delaware citizen – Forest Labs – is seeking redress for "injuries inflicted by out-of-state actors." *Burger King*, 471 U.S. at 473 ("A State generally has a 'manifest interest' in providing its residents with a convenient forum for redressing injuries inflicted by out-of-state actors.")

The minimal and expected burden to Orchid India of litigation in Delaware does not "clearly outweigh[]" the Plaintiffs' and Delaware's interests "in adjudicating the dispute in the forum." *Beverly Hills Fan*, 21 F.3d at 1568. Litigation is not an undesired, infrequent, and unintended consequence of Orchid India's generic pharmaceutical business – it is the focal point of the company's activities. Orchid India has identified litigation arising from "aggressively filing" ANDAs as one of its key business risks and files its ANDAs only after calculating "litigation risks and costs as well as business rewards." (Ex. 5 at OCP\_00000493; Ex. 3 at OCP\_00000597.) It considers

and Paragraph IV filings specifically as one of the "distinctive incentives" to operating in the United States market.

Such litigation would

necessarily take place in the United States, and Orchid India cannot complain that the burden to it of litigating in Delaware is any greater than it would be in any other state. Though Orchid India "will have to travel to the United States to defend itself, progress in communications and

transportation has made the defense of a lawsuit in a foreign tribunal less burdensome." Energy Transp., 2008 WL 78748, at \*5 (internal quotation marks omitted) (quoting Beverly Hills Fan, 21 F.3d at 1569).

Accordingly, and in view of the foregoing, this Court should exercise personal jurisdiction over Orchid India.

C. If The Court Declines To Exercise Jurisdiction Over Orchid India, The Action Against Orchid India Should Be Transferred To The District Of **New Jersey** 

Plaintiffs have made a prima facie case that exercising personal jurisdiction over Orchid India is consistent with Delaware's long-arm statute and the Due Process Clause. Should this Court decline to exercise jurisdiction over Orchid India, however, Plaintiffs respectfully request that the action against Orchid India be transferred to the District of New Jersey. A court may, in the interest of justice, transfer a case to any district "in which [the case] could have been brought," 28 U.S.C. § 1406(a), and this Court routinely does so, see, e.g., Stein v. Chemtex Int'l, Inc., No. 04-001-SLR, 2004 WL 722252, at \*3 (D. Del. 2004) (transferring case in the interest of justice because "[i]f the court were to outright dismiss the instant action, plaintiff may suffer a complete loss of her rights because the statute of limitations has run since plaintiff filed her suit in this district"); FS Photo, Inc. v. Picture Vision, Inc., 48 F. Supp. 2d 442, 450 (D. Del. 1999) (transferring case under section 1406(a) because there was no suggestion that the plaintiff brought the case in Delaware for an improper purpose).

Transferring the action against Orchid India to the District of New Jersey, rather than dismissing the action in its entirely, would clearly be in the interest of justice – especially given that this case was brought pursuant to the Hatch-Waxman Act. Under that Act, a patentee has a "strict statutory 45-day window" in which to file an infringement suit that will effect a stay on

FDA approval of an allegedly infringing ANDA. See Abbott Labs. v. Mylan Pharms., Inc., No. 05 C 6561, 2006 WL 850916, at \*8 (N.D. III. Mar. 28, 2006) (citing 21 U.S.C. § 355(j)(5)(B)(iii)). It is unclear, however, whether the stay of ANDA approval will remain in place if an action against a defendant, properly brought within the 45-day window, is subsequently dismissed for lack of personal jurisdiction after the 45-day period has expired. See PDL BioPharma, Inc. v. Sun Pharm. Indus., Ltd., No. 07-11709, 2007 WL 2261386, at \*2 (E.D. Mich. Aug. 6, 2007) (granting ANDA plaintiff's motion for a stay pending the resolution of a jurisdictional dispute in New Jersey in light of the Hatch-Waxman Act's "strict deadline" for filing suit and the "potentially harsh outcome" of possibly being precluded from filing "any action under the Act" if the New Jersey case was dismissed on jurisdictional grounds after the filing deadline); Abbott, 2006 WL 850916, at \*8 (acknowledging that the Hatch-Waxman Act "is silent, and the courts have not clarified, whether the patent holder loses its right to sue for patent infringement in the event its suit is dismissed for lack of personal jurisdiction after the 45-day period has expired"). Dismissal of this action against Orchid India, therefore, could have an unduly prejudicial result: approval of Orchid India's ANDA prior to the expiration of the statutorily-mandated stay. To avoid this result, the action against Orchid India should be transferred to the District of New Jersey.

Had Orchid India provided Plaintiffs with a Paragraph IV notice letter that satisfied the relevant statutory and regulatory requirements, including 21 U.S.C. § 355(j)(5)(B)(iii and 21 C.F.R. § 314.95(c)(7), Plaintiffs might have sued Orchid India in New Jersey. Orchid India's Paragraph IV Notice, however, failed to identify Orgenus as its U.S. regulatory agent for ANDA No. 90-044. (Ex. 28.) Instead, Orgenus was not identified to Plaintiffs as Orchid India's U.S.

regulatory agent until March 3, 2008, when Orchid India filed its motion to dismiss.<sup>32</sup> A dismissal of Orchid India that is not coupled with a transfer to the District of New Jersey would unfairly penalize Plaintiffs for Orchid India's blatant error. The "interest of justice" demands that this result be avoided. See 28 U.S.C. § 1406(a).

Orchid India has already provided a strong indication in its motion to dismiss that it would be amenable to personal jurisdiction in New Jersey: "Orchid India and Orgenus have not challenged jurisdiction in New Jersey." (D.I. 44 at 4-5 n.2.) Thus, in accordance with the requirements of § 1406(a), the action against Orchid India could have been brought in the District of New Jersey.

For these reasons, if the Court finds that it cannot exercise personal jurisdiction over Orchid India, it should transfer the action against Orchid India to the District of New Jersey.

<sup>32</sup> Though Orchid India contends it "publicly disclosed" that Orgenus was its agent for purposes of ANDA No. 90-044 by virtue of the FDA's posting of its suitability petition online (D.I. 44 at 5), FDA regulations require the ANDA filer to identify its agent in its Paragraph IV notice precisely to avoid forcing the patentee and NDA holder to hunt for facts that may be jurisdictionally relevant during the extremely short 45-day window for filing suit. See 21 C.F.R. § 314.95(c)(7).

### V. <u>CONCLUSION</u>

For all of the foregoing reasons, Orchid India's motion to dismiss should be denied. In the alternative, if Orchid India's motion to dismiss is granted, Plaintiffs respectfully request that their claims against Orchid India be transferred to the District of New Jersey pursuant to 28 U.S.C. § 1406(a).

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June 27, 2008

### **CERTIFICATE OF SERVICE**

I hereby certify that on July 3, 2008 I electronically filed the foregoing with the

Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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I further certify that I caused to be served copies of the foregoing document on

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